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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,848	03/26/2004	Stuart A. Lipton	507 US	9106

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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
04/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@adamaspharma.com

Office Action Summary	Application No.	Applicant(s)	
	10/810,848	LIPTON ET AL.	
	Examiner	Art Unit	
	CARLIC K. HUYNH	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20 September 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-17 are pending in the application, with claims 11-14 having been withdrawn from consideration, in response to the restriction requirement submitted on August 9, 2007. Accordingly, claims 1-10 and 15-17 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election without traverse of the claims of Group I, namely claims 1-10 and 15-17, in the reply filed on January 8, 2008 is acknowledged.

Claims 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on January 8, 2008.

3. Applicants' election of: (1) memantine as the species of an uncompetitive NMDA receptor channel antagonist in the reply filed on January 8, 2008 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-10 and 15-17 are being examined on the merits herein.

The election/restriction requirement is deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on September 20, 2005, is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-10 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. (US 6,071,966) in view of Paul et al. (The Journal of Pharmacology and Experimental Therapeutics, 2002, Vol. 302, No. 1, pp. 50-57 as cited in the IDS) and Thompson (Current Opinion in Neurology, 1998, Vol. 11, pp. 305-309).

Gold et al. teach a method of treating multiple sclerosis comprising administering NMDA receptor antagonists (column 36, lines 24-38). The composition is administered orally to humans at 1-1000 mg daily (column 19, line 45; column 19, line 66; and column 20, line 45). Although

the compound taught by Gold et al. is not memantine specifically, Gold et al. discloses memantine used as a control in their experiments (see Tables 7-9).

Gold et al. does not teach memantine specifically.

Paul et al. teach memantine is a NMDA receptor antagonist (abstract). Paul et al. also teach memantine can be used to treat multiple sclerosis (abstract).

Thompson is used solely to show the symptoms of multiple sclerosis are known in the art. Thompson teaches the symptoms of multiple sclerosis include cognitive dysfunction, fatigue, temperature lability, visual disturbance, speech/swallowing disturbance, poor dexterity (e.g. weakness, tremor, sensory disturbance), bladder/bowel/sexual dysfunction, poor mobility(e.g. weakness, spasticity, ataxia), and pain (page 305).

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the compounds of Gold et al. to contain memantine and to teach the symptoms of multiple sclerosis with the expectation of obtaining at least an additive effect, because memantine is known to be used in the treatment of multiple sclerosis as shown by Gold et al. and Paul et al. and the symptoms of multiple sclerosis are known as shown by Thompson.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Regarding diagnosing a patient as recited in claim 3 and to enable an observation of a reduction in the symptom as recited in claim 17, a skilled artisan such as a physician would be able to diagnose a patient with multiple sclerosis and to administer tests to observe any improvements of the symptoms in the patient. Thus it would be obvious that the skilled artisan can diagnose and observe the progress of multiple sclerosis patients.

Regarding the amount of NMDA receptor channel antagonist as recited in claims 7-10 and 17, Gold et al. teach the NMDA receptor antagonist composition is administered at 1-1000 mg daily (column 20, line 45) and Paul et al. teach memantine is a NMDA receptor antagonist that can be used to treat multiple sclerosis (abstract), which closely meets the amount of NMDA receptor channel antagonist in the composition set forth in instant claims 7-10 and 17. It is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the NMDA receptor antagonist (memantine) provided in a composition, according to the guidance set forth in Gold et al. and Paul et al., to provide a composition that meets the amount of NMDA receptor channel antagonist in a composition as recited in claims 7-10 and 17. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 223, 235 (CCPA 1955).

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2, and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 83 and 90 of copending Application Went et al. (11/285,905).

The instant claims are directed to a method of treating multiple sclerosis comprising administering memantine.

The claims of Went et al. (11/285,905) are directed to a method of administering memantine comprising memantine and a component that sustains release of memantine to a patient with multiple sclerosis.

It would have been obvious to one of ordinary skill in the art that for the treatment of a disease (multiple sclerosis), the composition (memantine) has to be administered and therefore instant claims and claims in the copending application of Went et al. (11/285,905) are obvious variants. Moreover, the open language of "comprising" in the instant claims allows for other compounds, such as a component that sustains release of memantine, to be used in the method.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

6. Claims 1, 2, and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-10 of copending Application Went et al. (11/827,251).

The instant claims are directed to a method of treating multiple sclerosis comprising administering memantine.

The claims of Went et al. (11/827,251) are directed to a method of treating multiple sclerosis comprising administering memantine and a fumarate agent.

It would have been obvious to one of ordinary skill in the art that for the treatment of a disease (multiple sclerosis), the composition (memantine) has to be administered and therefore instant claims and claims in the copending application of Went et al. (11/827,251) are obvious variants. Moreover, the open language of "comprising" in the instant claims allows for other compounds, such as a fumarate agent, to be used in the instant method. As such, it would be obvious to the skilled artisan that the instant method can include a fumarate agent.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

7. Claims 1, 2, and 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16, 18, 19, 26, and 31 of copending Application Went (11/884,516).

The instant claims are directed to a method of treating multiple sclerosis comprising administering memantine.

The claims of Went (11/884,516) are directed to a method of treating multiple sclerosis comprising administering memantine and a multiple sclerosis agent.

It would have been obvious to one of ordinary skill in the art that for the treatment of a disease (multiple sclerosis), the composition (memantine) has to be administered and therefore instant claims and claims in the copending application of Went (11/884,516) are obvious variants. Moreover, the open language of "comprising" in the instant claims allows for other compounds, such as a multiple sclerosis agent, to be used in the instant method. As such, it would be obvious to the skilled artisan that the instant method can include a multiple sclerosis agent.

This is a provisional double patenting rejection since the conflicting claims have not been patented.

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

ckh